

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS
LIABILITY LITIGATION

MDL No. 2419
Dkt. No. 1:13-md-2419 (FDS)

THIS DOCUMENT RELATES TO:

All Actions

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW
IN SUPPORT OF PROPOSALS FOR PLAINTIFF'S
PROFILE FORM, DISCOVERY PROTOCOLS, AND RELEASES**

I. INTRODUCTION¹

Despite months of meeting and conferring on the form of a plaintiff fact sheet/profile form, the parties have been unable to reach agreement. The Plaintiffs' Steering Committee (the "PSC") requests the Court's assistance in the development of this key form and other important documents necessary to advance this litigation.

The PSC has made significant concessions, resulting in a questionnaire that provides defendants far more information than the PSC believes is necessary to serve the intended purpose of this fact sheet/profile form: facilitating the selection of representative cases to be placed in a trial pool that will then go onto full discovery. The defendants continue to take the position that the profile form must include on additional information that, the PSC believes, is unduly burdensome and irrelevant to this limited purpose; the defendants are now requesting more information than in the profile form that they previously submitted to this Court.

¹ The PSC was unable to electronically file this submission on Friday, January 24, 2014 due to the nationwide disruption to the U.S. Court's CM/ECF system. As a result, the PSC submits this filing as soon as practicable on Monday morning. The PSC's efforts to file on Friday are more fully described in the contemporaneously filed declaration of Benjamin A. Gastel ("Gastel Decl.").

Further, because discussions centered on the plaintiff fact sheet/profile form have dominated the parties' meet and confer sessions, the parties have been unable to reach agreement on many of the other items necessary to move this case forward.

Cognizant of the need for victims of this national tragedy to obtain swift justice for the wrongs committed against them, the PSC requests that the Court rule on the propriety of the proposed profile form, the related releases that will be used with this document and discovery protocols that will ensure the advancement of this litigation. To this end, the PSC submits for the Court's approval the following documents:

- 1) Plaintiff profile form (the "PPF") to be completed and used to select bellwether cases;
- 2) Deposition protocol to facilitate the scheduling and conduct of depositions;
- 3) ESI protocol to govern the production of electronically stored information in discovery;
- 4) Medical records releases to be used in conjunction with this PPF;
- 5) Employment records release to be used by plaintiffs making lost wage claims;
- 6) Insurance records release for Plaintiffs that have previously been awarded disability or other benefits;
- 7) Worker's compensation records release to be used by Plaintiffs that have previously been awarded such benefits; and
- 8) IRS tax records release.

To be clear, the PSC does not maintain that these documents are the sum total of discovery that defendants are entitled to in this MDL. Rather, the purpose of these documents is to facilitate the selection of representative cases to be placed in a trial pool that will then go onto full discovery. The above proposal more than satisfies this limited but important purpose.

II. BACKGROUND

The parties have engaged in an extensive meet and confer process that began in mid-October.² A full and detailed explanation of this meet and confer is more fully set forth in the contemporaneously filed declaration.³ Although this meet and confer originally began with only counsel for certain Tennessee defendants participating, the PSC has consistently invited all defense counsel to participate in this meet and confer.⁴

In November and December of last year, the parties filed competing proposals with the Court.⁵ The parties extensively discussed these proposals at the December status conference. Thereafter, Judge Saylor entered an order referring these matters to Magistrate Boal stating the following:

Having reviewed the competing proposals for fact sheets, the Court is of the view that the proposed form suggested by the PSC would not provide sufficient information to make a meaningful analysis of a case for purposes of selecting potential “bellwether” cases...It is by no means clear, however, that the form proposed by defendant would provide an appropriate degree of information or whether it sweeps so broadly as to require the production of information that is of marginal materiality or relevance.⁶

Heeding Judge Saylor’s instruction, the PSC now offers a new PPF containing approximately five additional pages of material, pulled from defendant’s original fact sheet, that was not contained in plaintiff’s original proposal.⁷ This more than doubled the amount of information the PSC believes is strictly necessary for the profile form.⁸

² Gastel Decl. ¶ 2.

³ Gastel Decl. ¶¶ 2-12 and Exhibits 1-12.

⁴ See e.g., Gastel Decl. ¶¶ 5-6 and Exs. 3-4,

⁵ See Dkt. No. 592 and 617.

⁶ Dkt. No. 722 at P. 2-3.

⁷ Gastel Decl. ¶ 7 and Ex. 5; and Ex. 1 attached hereto.

⁸ Gastel Decl. ¶ 7 and Ex. 5 and Ex. 1 attached hereto.

On the other hand, on January 21, 2014, the defendants circulated a final version of their proposed plaintiff fact sheet, which incorporated some of the agreed changes on verbiage but did not contain any substantive changes on the scope and number of requests.⁹ In other words, the form now proposed by defendants is substantially the same form (with some additional requests) offered before the December status conference.¹⁰

III. SUMMARY OF PSC'S PROPOSED FORMS

For the Court's convenience, the PSC attaches to this filing the clean and final version of the forms it proposes to use. A summary of those forms follows:

Exhibit 1: Plaintiff Profile Form (the "PPF"), to be used by plaintiffs who file cases in this MDL and used to allow the parties to make meaningful selections for cases that will proceed to full discovery.

Exhibit 2: Deposition Protocol to be used to facilitate the scheduling and conduct of depositions.

Exhibit 3: ESI Protocol, to govern the searching and production of electronically stored information in discovery;

Exhibit 4: Medical Records Release, to be submitted by plaintiffs along with the PPF;

Exhibit 5: Employment Records Release, to be submitted with the PPF only by plaintiffs pursuing claims involving lost wages;

Exhibit 6: Insurance Disability Records Release, to be submitted with the PPF only by plaintiffs indicated they have been awarded disability benefits or pursued disability benefits in the past five years;

Exhibit 7: Worker's Compensation Records Release, to be submitted with the PPF only by plaintiffs indicated they have been awarded worker's compensation benefits or pursued permanent total or permanent partial disability benefits in the past five years;

Exhibit 8: IRS Tax Records Release, to be submitted with the PPF only by plaintiffs pursuing claims involving lost wages.

⁹ Gastel Decl. ¶ 11 and Ex. 10.

¹⁰ Compare Gastel Decl. Ex. 10 to Dkt. No. 592-4.

IV. ARGUMENT

I. The PSC's Proposed PPF Significantly Expands On Its Previous Proposal And Serves Judge Saylor's Intended Purpose To Allow A "Meaningful Analysis" Of A Case For Purposes Of Selecting Potential Bellwether Cases.

As Judge Saylor noted in his order referring the development of a fact sheet/profile form to Magistrate Boal, "the principal purpose[] of the fact sheet is to identify a subset of cases for selection as possible 'bellwether' cases for trial."¹¹ Originally, the PSC proposed that the profile form to be used to make such selections be the "Confidential Personal Injury or Wrongful Death Claim Information Form" (the "Bankruptcy Addendum") along with a HIPAA compliant medical authorization.¹²

The Bankruptcy Addendum is a four page document providing robust information on the facility where a plaintiff received an injection, the nature of a plaintiff's claim, the injuries sustained, and the damages sought by a plaintiff. Every plaintiff in this MDL presumably filed a Bankruptcy Addendum with their Proof of Claim form by January 15, 2014.

Cognizant of Judge Saylor's instruction, the PSC provided substantially more information in the PPF form it now submits for approval. The new PPF form is approximately 9 pages in length, more than double in size than the original PPF form proposed by the PSC. The additional information now requested in the PPF is taken almost verbatim from the fact sheet offered by the Defendants.

The new PPF form includes significant disclosures related to employment history, insurance and disability history, education history, family history, and medical history. Requests 8 through 28 are pulled virtually verbatim from defendant's original proposed fact sheet.¹³

¹¹ Dkt. No. 772 at P. 2.

¹² Dkt. No. 617 at P.8.

¹³ Compare Exhibit 1, PPF to Dkt. No. 592-4.

The new PPF also agrees to provide an employment release, a medical release, and a disability/worker's compensation records release that were not previously included.

The new PPF also includes two additional document requests not previously included in the PSC's proposed fact sheet.

These are significant concessions to the defendants, as the PSC does not believe that much of this information is necessary to serve the "principal purpose of the fact sheet [which] is to identify a subset of cases for selection [of] 'bellwether' cases for trial."¹⁴

These concessions require disclosure of more information than that required by the profile form recently entered by another judge in this district in another mass tort multi-district litigation pending here. Specifically, in *In re Fresenius Granuflo/Naturalyte Dialsate Products Liability Litigation*, Case No. 1:13-MD-2428, Judge Woodlock entered an approximately four page fact sheet that contained none of the employment history, medical history, education history, and family background information or the employment record, insurance record, worker's compensation record, and/or tax record releases the PSC has agreed to produce in this litigation.¹⁵

In short, the new proposed PPF significantly expands on the information to be used in the bellwether process, serving the intended purpose of this form: namely, to allow the parties sufficient information to make informed bellwether selections.

To be clear, the PSC is not now, nor has it ever, suggested that the PPF represents the only information the defendants may obtain from plaintiffs in discovery in this litigation. The PSC recognizes that additional case-specific discovery regarding plaintiffs will be needed once a case is selected as a potential bellwether, but the PPF should be limited to that information

¹⁴ Dkt. No. 722 at 2.

¹⁵ Gastel Decl. ¶ 13 and Ex. 13.

needed to make an informed decision on that issue. The PSC maintains that its newly proffered PPF more than serves this intended purpose.

II. The Plaintiff Fact Sheet Proposed By the Defendants Is Far Too Broad.

As can be seen from above, the PSC has made significant concessions in its good faith attempt to resolve this dispute. On the other hand, the defendant has not made a single such concession. The defendants' proposed fact sheet in December was 18 pages long and contained 57 enumerated requests along with 21 requests for production.¹⁶ The defendants' newly proposed fact sheet is 18 pages long, contains 59 enumerated requests along with 21 requests for production.¹⁷ It is virtually the exact same document, with one material exception. It includes additional requests in the medical information section for "cirrhosis, hepatitis, kidney failure, and depression."

The PSC continues to maintain that defendants' proposed document sweeps far more broadly than is necessary to serve the purpose of this document, and unnecessarily intrudes on individual Plaintiffs at this time.¹⁸ Here are a few examples of defendants' overreaching:

- **Requests 26 and 27** both violate Federal and State law, in that they require a Plaintiff to disclose medical information *about their relatives*.¹⁹ Congress, in passing HIPAA, recognized that individuals are entitled to a high expectation of privacy when it comes to their personal health information.²⁰ Many states have long held that a defendant may not make such an inquiry of a plaintiff for the simple reason that an individual's

¹⁶ See Dkt. No. 592-4.

¹⁷ Gastel Decl., ¶ 11 and Ex. 10; *see also* Dkt. No. 592-4.

¹⁸ See Dkt. No. 617 for a more substantive discussion. Because the plaintiff fact sheet offered by defendants now is virtually the same as the one offered in December, all of the PSC's arguments against this form continue to apply.

¹⁹ See *e.g.*, *Dierickx v. Cottage Hospital Corp.*, 152 Mich. App. 162 (Ct. App. Mich. 1986) (preventing discovery of family members' medical histories in personal injury lawsuit).

²⁰ See *e.g.*, *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 348, 354 (4th Cir. 2003) ("Recognizing the importance of protecting the privacy of health information in the midst of the rapid evolution of health information systems, Congress passed HIPAA in August 1996.").

medical privilege is not waived when a relative files a lawsuit.²¹

Defendants' insist that a plaintiff disclose if any child, parent, sibling, or grandparent has been diagnosed with HIV/Aids, arthritis/joint pain, chronic pain, diabetes, heart attack, cardiac disease, high cholesterol, high blood pressure, blood clots, coronary artery disease, congestive heart failure, deep vein thrombosis, vascular disease, transient ischemic attack, stroke or other diseases. Imposing this impermissible disclosure on every Plaintiff in this MDL is simply without merit.

- **Request 50** requires a plaintiff to describe his alcohol use over the course of the past 10 years if the plaintiff has consumed a single alcoholic beverage during that time period. Aside from no description in any literature of a relationship between the development and progression of a fungal related infection and chronic alcohol abuse, requiring every plaintiff to disclose whether or not they are a teetotaler is more than could reasonably be expected even of those individuals chosen as bell-weather.
- **Requests 52 and 54** require a plaintiff to provide essentially a full medical history for all illnesses and identify a host of medications that the patient may or may not have taken in the past ten years. The PSC cannot conceivably see how a patient receiving a steroid injection, for example, to combat a bee sting in 2004 has any relevancy whatsoever to any claim made in this litigation.

The above list is illustrative only. Numerous other requests in defendants' proposed PFS are equally broad and/or not reasonably tailored to lead to the discovery of admissible evidence. The

21 additional requests for production are similarly unbounded:

- **Request 6** requires a plaintiff to provide all documents related to any disability or worker's compensation claim filed by the plaintiff without restriction on time or scope. A plaintiff that filed a worker's compensation claim in 1971 related to a foot injury sustained on the job that resulted in him missing 5 weeks of work but no permanent impairment would have to produce records from that worker's compensation despite those records having no conceivable relevance to any claim made in this litigation.

²¹ See e.g., *Dierickx*, 152 Mich. App. 162; *In re New York County DES Litigation*, 168 A.D.2d 44, 47, 570 N.Y.S.2d 804, 805 (1991) ("The mere fact that a relative, distant or near in terms of kinship, has commenced a medical malpractice action alleging a birth defect should not subject all her relatives to the 'long arm' reach of the law authorizing their medical histories opened to all."); *Kunz v. S. Suburban Hosp. & Levie*, 326 Ill. App. 3d 951, 956 (Ill. App. 2001) ("[F]iling a medical malpractice lawsuit on behalf of a child, even when a genetic cause independent of medical malpractice may become an issue, does not thereby waive the physician-patient privilege in favor of the child's siblings.");

- **Request 19** requires a plaintiff to produce all documents related to any benefit a plaintiff has received in the past from any illness or injury from any source unrestricted by time and scope. This requires plaintiffs to produce medical insurance benefit information from every trip to the doctors office for every cold the plaintiff has suffered in their entire life.
- **Request 21** requires a plaintiff to produce every document the plaintiff, or plaintiff's attorney has obtained from any defendant in this lawsuit. Taken on its face this would require the reproduction of likely hundreds of thousands of pages of documents, documents that should already be in the possession of all defendants, by every plaintiff in this litigation. This is patently unworkable and obviously unnecessary.

In short, because the new proposed form is not in any material fashion different from the previous form, it is not a surprise that this "new" proposal suffers from the same defects originally identified by the PSC: it is unnecessarily long, seeks irrelevant information of the plaintiff and privileged information from non-parties, and is simply too burdensome for every plaintiff in this MDL to complete.

As Judge Saylor cautioned in his order, this form should not "sweep[] so broadly as to require the production of information that is of marginal materiality or relevance."²² While the PSC has heeded this Court's instruction to compromise on the scope of a fact sheet, the defendants have not done so. As a result, the PSC respectfully requests that the Court enter the PSC's proposed form as opposed to the unnecessarily detailed form offered by the defendants.

III. The PSC Requests The Court Enter The Additional Releases And Protocols Attached To This Form.

The PSC also requests the Court enter additional protocols and releases to be used in this MDL.²³ The PSC first elicited comments from the defendants on some drafts of these documents

²² Dkt. No. 722 at P. 3.

²³ Both the PSC and defense counsel have confirmed they will continue to work on the context of these releases and hope that this meet and confer can be more fruitful than the meet and confer on fact sheets. Nevertheless, the PSC submits these forms now in order to ensure they are properly before the Magister for the scheduled February 6, 2013 hearing.

months ago. Due to the prolonged discussions surrounding the fact sheets and profile forms, the parties have not had meaningful exchanges on protocols and form of releases. Nevertheless, the PSC proposes the following forms, attached hereto, for use in the MDL. These include the following:

Deposition Protocol: The PSC first circulated this document to defense counsel on November 27, 2013. The PSC received only two meaningful responses to this document,²⁴ the most substantive of which was received on January 16, 2013. The PSC incorporated some of the requested in the attached deposition protocol.

ESI Protocol: The PSC circulated its ESI protocol on November 22, 2013 to certain defendants and all defendants on November 27, 2013. To date, except for a brief discussion on the December 4, 2013 meet and confer call, the PSC has not received a single substantive response to this protocol. Meanwhile, defendants who have been served with document requests have refused to provide responsive electronic documents to those requests until and unless an ESI Protocol is in place.

Medical Release: The PSC first produced its form medical release on November 27, 2013. The major disputed issues related to the medical release involve: 1) timing; 2) scope; and 3) production recipient. The PSC maintains that the medical release should be limited to 5 years, should not include psychological, sexual abuse, and drug/alcohol addiction records, and should be produced to the HIPAA compliant vendor identified in the Court's Qualified Protective Order.²⁵ Defendants maintain that record should be produced for 10 years, there should be no limit on records that must be produced, and that they should receive records directly from

²⁴ One response was received on December 10, 2013 from the Trustee, thereafter the PSC recirculated its draft and the Trustee did not provide additional comments on the deposition protocol. Gastel Decl. ¶ 10, Exs. 8 and 9.

²⁵ Dkt. No. 192.

healthcare providers. The PSC also originally maintained that HIV/AIDS records should not be produced, but in an attempt to resolve this dispute, the PSC agreed to produce these records.²⁶ In further attempts at solving this impasse, the PSC also offered that if the PSC's restrictions on records were adopted, it would concede that production could go directly to the defendants and did not have to go through the HIPAA compliant vendor.²⁷ Defendants have not provided any feedback on this offer.

Employment Release: The PSC made minor edits to the employment releases offered by defendants. The PSC expects that its minor changes to the employment release will be accepted by the defendants.

Disability/Workers' Compensation Records Releases: The major disagreement on this issue is timing and scope. The PSC maintains that only the last five years of records related to requests for such benefits should be disclosed and has agreed that awards of these benefits should be disclosed regardless of the timing of the award. Defendants maintain that the records releases should cover ten years of claims, even though those claims were denied.

Tax Records Release: The parties agree to use the IRS form for tax records release and the PSC maintains that the release should be limited to the last four years of tax records.

The PSC proposed versions of these documents are attached to this Memorandum. Redlines of the PSC's proposal and the defendants proposals are attached to the Gastel Decl.²⁸

The PSC requests the immediate adoption of these forms so that this case can proceed forthwith. These documents are meant only to facilitate the selection of cases that proceed to full discovery and ultimate selection bellwether cases for trial. The PSC has agreed to provide far

²⁶ Gastel Decl. ¶ 14.

²⁷ Gastel Decl. ¶¶ 5, 12 and Exs. 3 and 11.

²⁸ Gastel Decl. ¶ 12 and Ex. 12.

more information than is customary provided in this preliminary process, and the PSC agrees that additional case-specific discovery over a plaintiff should proceed if and when a given case is selected for potential bellwether status. This approach is reasonable, fair, and satisfies the primary goal of the fact sheet: to provide information to make meaningful and informed choices among plaintiffs, to achieve a representative set of bellwether cases.

IV. CONCLUSION

In light of the foregoing, the PSC respectfully requests that the Court enter an order adopting the following documents attached to this Memorandum for use in this MDL 1) Plaintiff Profile Form; 2) Deposition Protocol; 3) ESI Protocol; 4) Medical Records Release; 5) Employment Records Release; 6) Insurance Records Release; 7) Worker's Compensation Records Release; and 8) IRS tax records release.

Date: January 27, 2014

Respectfully submitted:

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Kristen Johnson Parker, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: January 27, 2014

/s/ Kristen Johnson Parker
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